

DETAILED ACTION

1. Applicant's amendment and remarks filed October 15, 2009 are acknowledged.
2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with applicant's representative Mr. Eli Weiss on December 21, 2009 (see attached interview summary). In this interview, applicant's representative and the examiner discussed the claim amendments of October 15, 2009 and how the claims could be further amended to address the outstanding rejections of record, particularly the 35 U.S.C. § 112, 1st and 2nd paragraph issues associated with the "Jianye-2" recitation. After discussing the critical elements of the claim that distinguish the claimed therapeutically effective composition comprising an isolated and purified antibody from the art, i.e., the specificity of the claimed antibody for SEQ ID NO: 1 and the biological effects of the claimed antibody on the α -subunit of the Na^+/K^+ -ATPase, applicant's representative and the examiner agreed upon claim language sufficient to address this aspect of the outstanding rejections. Moreover, applicant's representative and the examiner discussed the outstanding rejection as to claim 4 and agreed upon claim language sufficient to address this aspect of the outstanding rejection.

The agreed upon allowable claims are put forth in the examiner's amendment that follows.

EXAMINER'S AMENDMENT

3. Claims 8-47 have been canceled.
4. Claims 1, 3, 4 and 7 have been replaced with the following rewritten claims:

Claim 1. A therapeutically effective composition comprising an isolated and purified antibody which is specifically made against the synthetic amino acid sequence RSATEEEPPNDD (SEQ ID NO: 1), wherein the binding of said antibody in a therapeutically effective amount to the α -subunit of the $(\text{Na}^+ + \text{K}^+)$ -ATPase enzyme increases myocyte intracellular diastolic or systolic calcium without inhibiting $(\text{Na}^+ + \text{K}^+)$ -ATPase enzyme activity.

Claim 3. The therapeutically effective composition of claim 1, wherein the binding of said antibody in a therapeutically effective amount to the α -subunit of the $(\text{Na}^+ + \text{K}^+)$ -ATPase enzyme increases myocyte intracellular diastolic or systolic calcium without inhibiting $(\text{Na}^+ + \text{K}^+)$ -ATPase enzyme activity and further exerts a positive inotropic effect in cardiac myocytes or in a heart for the treatment of heart failure or heart muscle contractile disorders.

Art Unit: 1644

Claim 4. The therapeutically effective composition of claim 1, wherein said antibody is specifically made against the synthetic amino acid sequence RSATEEPPNDD (SEQ ID NO: 1), said synthetic amino acid sequence being a component of a vaccine.

Claim 7. The therapeutically effective composition of claim 1 wherein said composition can be administered to a mammalian patient in a therapeutically effective amount for the treatment of heart failure or heart muscle contractile disorders.

5. Claim 48 has been added:

Claim 48. The therapeutically effective composition of claim 1 or 4, wherein said antibody is a polyclonal antibody, a monoclonal antibody, a humanized antibody or a human antibody.

6. Claims 1, 3, 4, 7 and 48 are allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ZACHARY SKELDING whose telephone number is (571)272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zachary Skelding/
Examiner, Art Unit 1644